UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,272	08/12/1999	SANDRA AUSTIN-PHILLIPS	09820.114	2404

7590 05/21/2002

INTELLECTUAL PROPERTY DEPARTMENT
DEWITT ROSS & STEVENS SC
FIRSTAR FINANCIAL CENTRE
8000 EXCELSIOR DRIVE SUITE 401
MADISON, WI 537171914

EXAMINER	
EPPS, JANET L	

ART UNIT	PAPER NUMBER
1635	12

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/373,272	AUSTIN-PHILLIPS ET AL.	
	Examiner	Art Unit	
	Janet L. Epps	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-22 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27 and 28* is/are allowed.

6)☒ Claim(s) *16-22,26,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 16-20, 21-22, 26 and 29-30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Van Ooyen et al. in view of Virki et al. (WO 93/20714), Henrissat et al., and Willmitzer et al. (PTO-1449), and further in view of Shiyaron et al. (GenBank Accesion No. E00389) and Thomas et al. for the reasons of record set forth in the Official Action mailed 6-05-2001.

It is also noted that the instant prior art rejection is maintained to the extent that the instant claims read on transgenic plants expressing *T. reesei* CBH I (SEQ ID NO: 9), and *A. cellulolyticus* endoglucanase E1 (SEQ ID NO: 8).

Applicant's arguments filed 9-07-2001 have been fully considered but they are not persuasive. Applicants traverse on the grounds that the combination of the Van Ooyen et al., Virki et al., Henrissat et al., and Willmitzer et al. references do not necessarily enable the transgenic expression of the particular polysaccharide-degrading enzymes explicitly recited in the claims. Applicants argue that the Office has inappropriately taken the position that "merely because Van Ooyen mentions the transgenic expression of any 'enzymes or combination of enzymes which are capable of degrading plant polysaccharides' the reference necessarily enables the expression of all such polysaccharide-degrading enzymes in a plant host....this is an overly broad interpretation of the Van Ooyen reference." To support Applicant's argument that the combined references do not sufficiently enable the claimed invention, Applicants cite the

teachings of Yan et al. which demonstrate the failure of using the Agrobacterium-mediated transformation system in transgenic *petunia hybrida*. According to Applicants the teachings of Yan et al. reveal a complete and utter lack of success using the Agrobacterium transformation system, since thy did not generate a single successful dicot transformant as evidenced by the co-suppression rate of 100%.

First in regards to the question of the prior art reference providing sufficient guidance and/or instruction to enable one of skill in the art to practice the claimed invention, it is noted that the teachings of the Van Ooyen et al. reference uses the same plant binary vector transformation system for expressing genes in plant tissue as described in Applicant's specification, namely the *Agrobacterium tumafacien* transformation system (Van Ooyen et al., col. 5, line 56; col. 7, lines 27-43). Applicant's own specification recites that "[T]ransformation of the plants can be accomplished by any means known to the art, including *Agrobacterium*-mediated transformation, particle bombardment, electroporation, and virus-mediated transformation....*Agrobacterium tumafaciens*...is the preferred strain for transformation." Applicants have not provided any clear evidence that it would require one of skill in the art undue experimentation to use the plant transformation system disclosed in Van Ooyen et al. to express the plant polysaccharide degrading enzymes according to SEQ ID NO: 8 and 9 in a either a tobacco plant or an alfalfa plant.

In regards to the Yan et al. reference, it is unclear how Applicants arrived at the conclusion that the *Agrobacterium* transformation system used by Yan et al. was unsuccessful, since the reference clearly states that the transformation system clearly produced successful transformants as indicated on page 4, and figure 2 of the specification. Therefore, Applicant's

assertion of unpredictability regarding the *Agrobacterium* transformation system is not supported by this reference. Although, some experimentation would be required to produce a genetically recombinant plant according to the present invention by following the guidelines set forth in the cited references in combination with what is known in the prior art, according to MPEP § 2164.06, "a considerable amount of experimentation is permissible, if it is merely routine.."

Additionally, Applicant's traverse the rejection of claim 26 on the grounds that the combined references do not teach a method of ensilement comprising the use of a transgenic plant. However, contrary to Applicant's assertions, teach the use of the enzymes according to the present invention in a method of ensilement, and further suggests a transgenic method of providing genes that encode these enzymes in a plant. One of skill in the art seeking a means to provide a continuous supply of degradative enzymes to a plant would have been motivated to design a transgenic plant expressing said enzymes.

Applicants argue that the combined references do not provide motivation for expressing plant polysaccharide degrading enzymes specifically for ensilage purposes. However, as stated above, the Willmitzer et al. reference provide teachings for the use of transgenic plants expressing enzymes, including cellulases, for the improvement of the nutritive value of feed, i.e. ensilage. Although, the term "ensilement" is not specifically mentioned in these references one of skill in the art would recognize that the teachings of Willmitzer et al. would necessarily encompass a method of ensilement.

Moreover, Applicants argue that the reliance upon the Henrissat reference is improper since the Vikri et al. reference directly contradicts the teaching of Henrissat et al. Applicant's point is uncertain since the invention of Vikri et al. is clearly drawn to improving the nutritional

value of crops by providing highly purified compositions comprising a combination of cellulolytic enzymes. Applicants base this conclusion on the first paragraph of the Vikri et al. reference, which describes the adverse effects of commercial products are caused by the presence of certain enzyme combinations in the commercial grade cellulases used in products. However, contrary to Applicant's assertions, this statement was stated in regards to the use of "commercial grade" combinations of cellulase enzymes. Vikri et al. disclose a means of fractionating commercial grade enzyme mixtures, which normally contain large numbers of enzymes to isolate enzymatic cellulase mixtures from material that is undesirable for the crop being treated (see page 30, lines 15-17). In regards to the teachings of Henrissat, Henrissat teaches that cellulase mixtures are desirable, as stated by Applicants. Therefore, there is agreement between the teachings of Vikri et al. and Henrissat et al.

Applicant's arguments are not sufficient to overcome the pending rejection of the instant claims as obvious over Van Ooyen et al. in view of Virki et al. (WO 93/20714), Henrissat et al., and Willmitzer et al. (PTO-1449), and further in view of Shiyaron et al. (GenBank Accesion No. E00389) and Thomas et al.

Conclusion

3. Claims 27-28 are allowable over the prior art, and in view of Applicant's filing of a terminal disclaimer over US Patent 5,981,835.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps, Ph.D.
Examiner
Art Unit 1635

JLE
May 17, 2002

SEAN McGARRY
PRIMARY EXAMINER
1635